REMARKS

Claims 22-55 are present in this application. Claim 22 is the only independent claim, and it is drawn to an active ingredient matrix. The remaining claims depend therefrom. The specification has been amended to provide support for limitations found in the claims as originally filed. Claims 22, 30 and 46 have been amended to better clarify the subject matter. Accordingly, Applicant respectfully submits that no new matter within the meaning of 35 U.S.C. 132 is added by the amendments.

Claims 22-55 stands rejected under 35 U.S.C. 112, first paragraph as being based a non-enabling specification. Claims 22-55 further stand rejected 35 U.S.C. 112, second paragraph as being indefinite.

With entry of the above amendments and following remarks, Applicant respectfully submits that the claims are now in condition for allowance.

1. Rejection of Claims 22-55

Under 35 U.S.C. 112, First Paragraph

Claims 22-55 stands rejected under 35 U.S.C. 112, first paragraph as being based on a non-enabling specification for the reasons set forth in the office action.

RESPONSE

Applicant respectfully traverses this rejection and requests reconsideration and withdrawal thereof.

Applicant has amended the specification to include proper support for the limitations "substantially free from other constituents" and "substantially free from salts" in claim 22 and the dependent claims. In particular, paragraph [023] of the specification has been amended to provide the support for these limitations.

The Examiner indicates that undue experimentation is needed to practice the present claims because, in paragraph [022], the specification recites that other active ingredients can be included in the matrix. However, Applicant respectfully submits that it is within the realm of knowledge of one of ordinary skill in the art to practice the present claims based on the solubilities of the other active ingredients to be included in the matrix. The active ingredient matrix of the present claims allows for retention of poorly water-soluble active ingredients within the body in order to aid in bioavailability of the active ingredient. Claim 22 specifies that the at least one active ingredient have a physiological medium solubility of less than 10 mg/ml. One of ordinary skill in the art would be able to include amounts of other active ingredients in the active ingredient matrix based on the

solubilities of the other active ingredients. Thus, while some experimentation **may be needed,** Applicant submits that the experimentation is not undue or overly burdensome.

Accordingly, Applicant submits that, with the amendment to the specification made herein, the claims are now based on an enabling specification. Accordingly, Applicant has thus removed the basis for this rejection, and respectfully requests reconsideration and withdrawal thereof.

2. Rejection of Claims 22-55

Under 35 U.S.C. 112, Second Paragraph

The Examiner has rejected claims 22-55 under 35 U.S.C. 112, second paragraph for the reasons set forth below.

> Regarding claims 22-55, the phrases "substantially free from other constituents" and "substantially free from salts" render the claims indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). It is suggested that applicant recite the specific amounts of the active ingredients that are present in composition.

RESPONSE

Applicant respectfully traverses this rejection and request reconsideration and withdrawal thereof.

The desired effect of a retarded release of active ingredients included in the matrix of collagen fibrils according to the invention is obtained due to the inherent characteristics of the combination of the matrix and ingredient(s), namely based on the poor solubility in water and body fluids of the latter. Thus, there is no necessity to add further components to provide, enhance or induce the desired characteristics like slow release of active ingredient and bio-resorbability of the matrix.

During processing of collagen fibrils to prepare the matrix, the processing conditions are selected in such a way that the collagen suspension is kept in a narrow pH range of between 3.5 and 4.8. Since demineralized water is used for rinsing or washing, there is no need for pH correction once the pH has been established. This removes the need for the addition of salt components to effect pH adjustment to the desired range. This results to an active ingredient matrix that is substantially free from such additional impurities and salts that could affect its performance. (see paragraph [23] of the specification). Thus, one of ordinary skill in the art will realize that, **due to the rinsing or washing with demineralized water**, the product will not contain any constituents other than the collagen fibrils carrier and the **active ingredients to be included**. Put another way, the rinsing

[redacted]

with demineralized water assures the purity of the carrier and active ingredient.

This concept (rinsing with demineralized water to achieve a product substantially free of other constituents and salts) is exemplified in the example on pages 6 and 7 of the description, under the heading "Rinsing Stage." The product from the swelling stage is rinsed with demineralized water. Following five rinses with demineralized water, the concentration of the acetic acid drops from 6.37 to 0.08 mg/l in the first test, and from 6.40 to 0.05 mg/l in the second test. Thus, the demineralized water has effectively removed the acetic acid from the product. As is shown in the example, one of ordinary skill in the art is easily able to determine the purity of the product based on the number of washes.

Further, claim 22 has been amended to clarify that the limitations found after the particular phrase are, indeed, part of the claimed subject matter.

Accordingly, Applicant respectfully submits that claims 22-55 are definite based on the language contained within the claims. Applicant respectfully requests reconsideration and withdrawal of the rejection thereof.

Regarding claim 30, the phrase "it contains at least one less poorly soluble or easily soluble active ingredient" contain relative terms which render the claim indefinite. The

[redacted]

term "less" and "easily" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

RESPONSE

Applicant respectfully traverses this rejection and requests withdrawal and reconsideration thereof.

Applicant has amended claim 30 to remove the offending term, thus removing the basis for this rejection. Thus, Applicant requests reconsideration and withdrawal thereof.

Regarding claim 46, it is unclear as to what applicant intend to convey since applicant is claiming salts of the compounds "clindamicin-palmitate, clindamicin-palmitate hydrochloride and gentamicin-crobefat" in claim 46. Clarification is requested.

RESPONSE

Applicant respectfully traverses this rejection and requests withdrawal and reconsideration thereof.

Applicant respectfully submits that claim 46 is definite and clear as written. Claim 45 specifies that the antibiotic is an aminoglycoside antibiotic. Claim 46 depends from claim 45 and specifies that the one or more aminoglycoside antibiotic is selected from the group consisting of clindamicin-palmitate, clindamicin-palmitate hydrochloride and gentamicin-crobefat, which

[redacted]

are listed in the specification as examples of aminoglycoside antibiotics. Thus, there is a logical progression to the claims of claiming from a broad concept (i.e., claiming an antibiotic) to a narrower concept (i.e., claiming an aminoglycoside antibiotic) to an even narrower concept (i.e., claiming specific aminoglycoside antibiotics). Applicant respectfully submits that this is clear from the claim, and that claim 46 is definite as amended above.

Accordingly, Applicant respectfully submits that the claims are definite in their scope, and respectfully requests reconsideration and withdrawal of these rejections.

CONCLUSION

In view of the foregoing, applicant respectfully requests the Examiner to reconsider and withdraw the rejections of the claims and to allow all of the claims pending in this application.

If the Examiner has any questions or wishes to discuss this matter, the Examiner is welcomed to telephone the undersigned attorney.

Respectfully submitted,
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